

EXHIBIT M

In the Matter Of:

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY

VIDEOTAPED DEPOSITION OF TERRY W. GRINDER, DPH

September 14, 2015



DISCOVERY
LITIGATION SERVICES
Court Reporting • Videography • Trial Presentations

100 Mayfair Royal
181 Fourteenth Street
Atlanta, GA 30309
404.847.0999

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY
VIDEOTAPED DEPOSITION OF TERRY W. GRINDER, DPH on 09/14/2015

Page 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND)
COMPOUNDING PHARMACY,) MDL No. 2419
INC. PRODUCTS LIABILITY) Master Docket No.:
LITIGATION) 1:13-md-2419-RWZ
)
THIS DOCUMENT RELATES TO:) Honorable Rya W. Zobel
All Actions)
)

VIDEOTAPED DEPOSITION OF:

TERRY W. GRINDER, DPH

Taken on behalf of the Plaintiffs

September 14, 2015

DISCOVERY LITIGATION SERVICES
100 Mayfair Royal
181 14th Street, NE
Atlanta, Georgia 30309
404-847-0999



DISCOVERY
LITIGATION SERVICES
Court Reporting • Videography • Trial Presentations
Nationwide Coverage

100 Mayfair Royal
181 Fourteenth Street
Atlanta, GA 30309
404.847.0999
www.DiscoveryLit.com

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY
VIDEOTAPED DEPOSITION OF TERRY W. GRINDER, DPH on 09/14/2015

Pages 2..5

Page 2	Page 4
<p>1 APPEARANCES:</p> <p>2 For the Plaintiffs:</p> <p>3 GEORGE NOLAN, ESQ.</p> <p>4 Leader, Bulso & Nolan, PLC</p> <p>5 414 Union Street</p> <p>6 Suite 1740</p> <p>7 Nashville, Tennessee 37219-1734</p> <p>8 615-780-4114</p> <p>9 gnolan@leaderbulso.com</p> <p>10</p> <p>11 DANIEL L. CLAYTON, ESQ.</p> <p>12 Kinnard, Clayton & Beveridge</p> <p>13 127 Woodmont Boulevard</p> <p>14 Nashville, Tennessee 37205</p> <p>15 615-297-1007</p> <p>16 dclayton@kcbattys.com</p> <p>17 For Saint Thomas Outpatient Neurosurgical Center, LLC;</p> <p>18 Howell Allen, a Professional Corporation; John W.</p> <p>19 Culclasure, M.D.; Debra V. Schamberg, RN; Specialty</p> <p>20 Surgery Center; Crossville, PLLC; Kenneth R. Lister,</p> <p>21 M.D.; Kenneth R. Lister, M.D., PC; and Donald E.</p> <p>22 Jones, M.D.:</p> <p>23 CHRISTOPHER TARDIO, ESQ.</p> <p>24 Gideon, Cooper & Essary, PLC</p> <p>25 315 Deaderick Street</p> <p> Suite 1100</p> <p> Nashville, Tennessee 37238</p> <p> 615-254-0400</p> <p> chris@gideoncooper.com</p> <p>For Saint Thomas Health, Saint Thomas Network, and Saint</p> <p>Thomas Hospital:</p> <p>AMY D. HAMPTON, ESQ.</p> <p>Bradley Arant Boult Cummings, LLP</p> <p>Roundabout Plaza, Suite 700</p> <p>1600 Division Street</p> <p>Nashville, Tennessee 37203</p> <p>615-244-2582</p> <p>ahampton@babbc.com</p>	<p>1 APPEARANCES (Continued):</p> <p>2 For Barry Cadden and Lisa Cadden:</p> <p>3 CALLAN STEIN, ESQ.</p> <p>4 Donoghue Barrett & Singal, PC</p> <p>5 One Beacon Street</p> <p>6 Suite 1320</p> <p>7 Boston, Massachusetts 02108</p> <p>8 617-720-5090</p> <p>9 cstein@dbslawfirm.com</p> <p>10</p> <p>11 For the South Bend Clinic, LLP, and Kathryn L.</p> <p>12 Park, M.D.:</p> <p>13 KYLE LAWRENCE, ESQ.</p> <p>14 Eichhorn & Eichhorn, LLP</p> <p>15 200 Russell Street</p> <p>16 Hammond, Indiana 46320</p> <p>17 219-931-0560</p> <p>18 klawrence@eichhorn-law.com</p> <p>19 For Anonymous Healthcare Provider No. 1:</p> <p>20 JOSEPH KLAUSING, ESQ.</p> <p>21 O'Bryan, Brown & Toner</p> <p>22 455 South Fourth Street</p> <p>23 Suite 1500</p> <p>24 Louisville, Kentucky 40202</p> <p>25 502-585-4700</p> <p> klausingj@obtlaw.com</p> <p>For Tim I. Chowdhury, M.D.:</p> <p>BARTHOLOMEW T. FREEZE, ESQ.</p> <p>Freund, Freeze & Arnold</p> <p>65 East State Street</p> <p>Suite 800</p> <p>Columbus, Ohio 43215-4247</p> <p>614-827-7300</p> <p>bfreeze@ffalaw.com</p> <p>For a Defendant Party:</p> <p>HEATHER KANNY, ESQ.</p> <p>Fraley & Fraley, LLP</p> <p>901 Main Street</p> <p>Suite 6300</p> <p>Dallas, Texas 75202</p> <p>214-761-6460</p> <p>hkanny@fraley-law.com</p>
Page 3	Page 5
<p>1 APPEARANCES (Continued):</p> <p>2 For Specialty Surgery Center and Kenneth R. Lister,</p> <p>3 M.D.:</p> <p>4 KENT E. KRAUSE, ESQ.</p> <p>5 Brewer, Krause, Brooks, Chastain &</p> <p>6 Burrow, PLLC</p> <p>7 611 Commerce Street</p> <p>8 Suite 2600</p> <p>9 Nashville, Tennessee 37203</p> <p>10 615-256-8787</p> <p>11 kkrause@bkbkblaw.com</p> <p>12</p> <p>13 For the Witness:</p> <p>14 DEVIN M. WELLS, ESQ.</p> <p>15 TOM AUMANN, ESQ.</p> <p>16 Tennessee Department of Health</p> <p>17 Office of General Counsel</p> <p>18 665 Mainstream Drive</p> <p>19 Second Floor</p> <p>20 Nashville, Tennessee 37243</p> <p>21 615-253-5988</p> <p>22 devin.m.wells@tn.gov</p> <p>23</p> <p>24 *The following attorneys appeared via telephone*</p> <p>25</p> <p>For Saint Thomas Health, Saint Thomas Network, and Saint</p> <p>Thomas Hospital:</p> <p>YVONNE K. PUIG, ESQ.</p> <p>Norton Rose Fulbright US, LLP</p> <p>98 San Jacinto Boulevard</p> <p>Suite 1100</p> <p>Austin, Texas 78701-4255</p> <p>512-536-2450</p> <p>yvonne.puig@nortonrosefulbright.com</p> <p>*The following attorneys appeared via video stream*</p> <p>For Defendants Ocean State Pain Management, PC, and</p> <p>Abdul R. Barakat, M.D.:</p> <p>THOMAS M. DOLAN, III, ESQ.</p> <p>Caplis, Connors & Carroll, PC</p> <p>18 Tremont Street</p> <p>Suite 330</p> <p>Boston, Massachusetts 02108</p> <p>617-227-0722 (Telephone)</p> <p>tdolan@ccclaw.org</p>	<p>1 Also Present:</p> <p>2 The Court Reporter:</p> <p>3 PAMELA P. WILLIS, TCCR NO. 229</p> <p>4 Discovery Litigation Services</p> <p>5 100 Mayfair Royal</p> <p>6 181 14th Street NE</p> <p>7 Atlanta, Georgia 30309</p> <p>8 404-847-0999</p> <p>9 nashvillecourtreporter@yahoo.com</p> <p>10</p> <p>11 The Videographer:</p> <p>12 MICHAEL MITCHELL</p> <p>13 VCE Legal Videography</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p>MOLLY MOORE</p>



DISCOVERY
LITIGATION SERVICES
Court Reporting • Videography • Trial Presentations

Nationwide Coverage

100 Mayfair Royal
181 Fourteenth Street
Atlanta, GA 30309
404.847.0999
www.DiscoveryLit.com

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY
VIDEOTAPED DEPOSITION OF TERRY W. GRINDER, DPH on 09/14/2015

Pages 6..9

Page 6			Page 8		
1	- INDEX -		1	- EXHIBITS -	
2	Witness	Page	2	Number	Description
3	TERRY W. GRINDER, DPH			No. 590	Tennessee Board of Pharmacy
4	Examination		3		Newsletter Dated December 2012.....
	By Mr. Nolan.....	11	4	No. 591	New England Compounding Center
5	Examination				Customer List.....
	By Mr. Tardio.....	37	5	No. 592	Rules of the Tennessee Board
6	Further Examination		6		of Pharmacy, Chapter 1140-9.....
	By Mr. Nolan.....	102	7		
7	Further Examination		8		
	By Mr. Tardio.....	118	9		
8	Further Examination		10		
	By Mr. Nolan.....	129	11		
9	Further Examination		12		
	By Mr. Tardio.....	137	13		
10	Further Examination		14		
	By Mr. Nolan.....	137	15		
11			16		
12			17		
13	- EXHIBITS -		18		
	Number	Description	19		
14	No. 526	NECC Document (Previously Marked)	20		
		(Retained by Counsel).....	21		
15			22		
	No. 572	Notice of Deposition and Subpoena....	23		
16			24		
	No. 573	T.C.A. 63-10-204.....	25		
17					
	No. 574	Hand-Drawn Diagram of			
18		Prescriber-Pharmacy-Patient			
		Relationship.....			
19					
	No. 575	NECC Prescription Order Form			
20		Dated July 24, 2012.....			
	No. 576	State of Tennessee Board of			
21		Pharmacy License of New England			
		Compounding Center.....			
22					
23					
24					
25					

Page 7			Page 9		
1	- EXHIBITS -		1	The videotaped deposition of TERRY W. GRINDER,	
2	Number	Description	2	DPH, was taken on behalf of the Plaintiffs on	
	No. 577	Rules of the Tennessee Board of	3	September 14, 2015, commencing at 10:01 a.m. and	
3		Pharmacy, Chapter 1140-3	4	concluding at 1:31 p.m., at the offices of Leader, Bulso	
	No. 578	Revised 2009.....	5	& Nolan, PLC, 414 Union Street, Suite 1740, Nashville,	
4			6	Tennessee, for all purposes under the Federal Rules of	
	No. 579	Rules of the Tennessee Board of	7	Civil Procedure.	
5		Pharmacy, Chapter 1140-7	8	The formalities as to notice, caption,	
		Revised 1999.....	9	certificate, et cetera, are not waived. All objections,	
6			10	except as to the form of the questions, are reserved to	
	No. 580	Tennessee Department of Health	11	the hearing.	
7		Licensure Verification Web Page.....	12	It is agreed that Pamela P. Willis, TLCR No.	
		Tennessee Department of Health	13	229, being a Notary Public and Court Reporter for the	
8		Licensure Verification Web Page	14	State of Tennessee, may swear the witness and that the	
	No. 581	With Barry Cadden Search Results....	15	reading and signing of the completed deposition by the	
9			16	witness are reserved.	
	No. 582	Tennessee Department of Health	17		
10		Board of Pharmacy Disciplinary	18		
		Actions Web Page.....	19		
11			20		
	No. 583	Massachusetts Board of Pharmacy	21		
12		Inspection Report.....	22		
			23		
13			24		
	No. 584	Tennessee Department of Health	25		
14		Helpful Links and Frequently Asked			
		Questions Web Page.....			
15					
	No. 585	Tennessee Board of Pharmacy			
16		Board Meeting Minutes			
		Dated January 22-23, 2014.....			
17					
	No. 586	Tennessee Department of Health			
18		Board of Pharmacy Web Page.....			
19					
	No. 587	Board of Pharmacy Emergency Rules....			
20					
	No. 588	Tennessee Department of Health			
21		Board of Pharmacy Featured			
		Links Web Page.....			
22					
	No. 589	Tennessee Board of Pharmacy			
23		March 2014 Newsletter.....			
24					
25					



DISCOVERY
LITIGATION SERVICES
Court Reporting • Videography • Trial Presentations

Nationwide Coverage

100 Mayfair Royal
181 Fourteenth Street
Atlanta, GA 30309
404.847.0999
www.DiscoveryLit.com

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY
VIDEOTAPED DEPOSITION OF TERRY W. GRINDER, DPH on 09/14/2015

Pages 10..13

Page 10	Page 12
<p>1 PROCEEDINGS</p> <p>2 MS. PUIG: I just want to say that Amy and</p> <p>3 I are appearing today on behalf of the Saint Thomas</p> <p>4 entities. And through the gracious consent of the ESC</p> <p>5 granted three weeks ago, I'm being allowed to appear as</p> <p>6 lead counsel remotely today. So I thank you for that</p> <p>7 opportunity, but I wanted to explain that I'm not just a</p> <p>8 listener today. So thank you so much. Appreciate it.</p> <p>9 (Discussion off the record.)</p> <p>10 THE VIDEOGRAPHER: All right. This is</p> <p>11 Disk No. 1 in the videotaped deposition of Dr. Terry</p> <p>12 Grinder, taken in the matter of New England Compounding</p> <p>13 Pharmacy, Inc., product liability litigation. The</p> <p>14 deposition is being held at Leader, Bulso & Nolan in</p> <p>15 Nashville, Tennessee. My name is Michael Mitchell, and</p> <p>16 I'm the videographer. The court reporter is Pam Willis.</p> <p>17 Could everybody please introduce</p> <p>18 yourselves for the record.</p> <p>19 MR. NOLAN: George Nolan for the</p> <p>20 plaintiffs.</p> <p>21 MR. TARDIO: Chris Tardio for the</p> <p>22 Tennessee Clinic defendants.</p> <p>23 MS. HAMPTON: Amy Hampton and Yvonne Puig</p> <p>24 on behalf of the Saint Thomas entities, including Saint</p> <p>25 Thomas Health, Saint Thomas Network, and Saint Thomas</p>	<p>1 A. Yes.</p> <p>2 Q. And I'd like to make the first exhibit, a copy</p> <p>3 of what we call the Notice of Deposition, as well as the</p> <p>4 subpoena, that's going to be Exhibit No. 572.</p> <p>5 (Exhibit No. 572 was marked.)</p> <p>6 BY MR. NOLAN:</p> <p>7 Q. And I don't have extra copies for everybody</p> <p>8 because everyone has already received it. But one of</p> <p>9 the things, Dr. Grinder, that was attached to the</p> <p>10 subpoena that you received is what we call a protective</p> <p>11 order.</p> <p>12 And that's an order of the Court that basically</p> <p>13 says that if -- if any of the lawyers reveal to you</p> <p>14 what's been designated confidential information in this</p> <p>15 litigation, then you'd be required to keep it</p> <p>16 confidential. In other words, you're not supposed to go</p> <p>17 out and post it on the Internet or talk about it outside</p> <p>18 this context.</p> <p>19 Do you understand that requirement?</p> <p>20 A. Yes.</p> <p>21 Q. All right. Where do you work?</p> <p>22 A. I work at the Tennessee Department of Health</p> <p>23 for the Tennessee Board of Pharmacy.</p> <p>24 Q. And how long have you worked there?</p> <p>25 A. Eleven years and six months.</p>
Page 11	Page 13
<p>1 Hospital.</p> <p>2 MR. CLAYTON: Daniel Clayton on behalf of</p> <p>3 the plaintiffs.</p> <p>4 MR. KRAUSE: Kent Krause on behalf of</p> <p>5 Specialty Surgery Center and Dr. Lister.</p> <p>6 MR. AUMANN: Tom Aumann from the Office of</p> <p>7 General Counsel for Dr. Grinder.</p> <p>8 MR. WELLS: Devin Wells, Deputy General</p> <p>9 Counsel, Tennessee Department of Health on behalf of</p> <p>10 Dr. Grinder.</p> <p>11 MS. PUIG: Yvonne Puig, Saint Thomas</p> <p>12 Entities, with Amy Hampton.</p> <p>13 THE VIDEOGRAPHER: Would the court</p> <p>14 reporter please swear in the witness:</p> <p>15 TERRY W. GRINDER, DPH,</p> <p>16 Having been first duly sworn, was examined and</p> <p>17 testified as follows:</p> <p>18 EXAMINATION</p> <p>19 BY MR. NOLAN:</p> <p>20 Q. Sir, would you please state your name.</p> <p>21 A. Terry Webb Grinder.</p> <p>22 Q. Dr. Grinder, we are here to take your</p> <p>23 deposition, and do you understand that you've been asked</p> <p>24 to appear and testify today pursuant to a subpoena</p> <p>25 that's been served on you?</p>	<p>1 Q. Okay. And are you a licensed pharmacist?</p> <p>2 A. I am.</p> <p>3 Q. And how long have you been a licensed</p> <p>4 pharmacist?</p> <p>5 A. For approximately 33 years.</p> <p>6 Q. And could you just give us a thumbnail sketch</p> <p>7 of your educational background and training in the field</p> <p>8 of pharmacy.</p> <p>9 A. Okay. I graduated from the University of</p> <p>10 Tennessee College of Pharmacy in 1982. I owned and</p> <p>11 operated some retail pharmacies as well as performed</p> <p>12 some nursing home and hospital pharmacy.</p> <p>13 In 2 -- in 1993 I became a chain pharmacist,</p> <p>14 worked for a chain for a number of years, and then</p> <p>15 became a district manager for a pharmacy for that chain.</p> <p>16 And in 2004, then I applied for and got the job</p> <p>17 with the Tennessee Board of Pharmacy as an investigator.</p> <p>18 Q. And, currently, what is your position with the</p> <p>19 Tennessee Board of Pharmacy?</p> <p>20 A. I am a pharmacist investigator.</p> <p>21 Q. All right. And what are your job duties?</p> <p>22 A. We do inspections. We investigate complaints.</p> <p>23 We do follow-up visits; compliance checks; various and</p> <p>24 sundry of pharmacies, manufacturers, wholesalers,</p> <p>25 distributors, both -- both retail and institutional</p>



DISCOVERY
LITIGATION SERVICES
Court Reporting • Videography • Trial Presentations

Nationwide Coverage

100 Mayfair Royal
181 Fourteenth Street
Atlanta, GA 30309
404.847.0999
www.DiscoveryLit.com

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY
VIDEOTAPED DEPOSITION OF TERRY W. GRINDER, DPH on 09/14/2015

Pages 14..17

<p style="text-align: right;">Page 14</p> <p>1 pharmacies, as well as drug researchers.</p> <p>2 Q. Okay. And who do you inspect?</p> <p>3 A. Any of our licensees are subject to be</p> <p>4 inspected. Typically, it's the facilities rather than</p> <p>5 the individuals.</p> <p>6 Q. Okay. And where are they typically located?</p> <p>7 A. The ones we actually inspect are in Tennessee.</p> <p>8 Q. Okay. And in addition to being a pharmacist</p> <p>9 investigator, have you held any other positions with the</p> <p>10 Tennessee Board of Pharmacy?</p> <p>11 A. I have also served as an interim director on</p> <p>12 three different occasions over my tenure, and I think</p> <p>13 the total time lapse was approximately about five years</p> <p>14 of my 11 plus --</p> <p>15 Q. I see.</p> <p>16 A. -- have been dual roles.</p> <p>17 Q. Okay. And so during the approximately five</p> <p>18 years of your 11 years with the board in which you</p> <p>19 served as interim director of the Board of Pharmacy,</p> <p>20 could you explain what your duties included.</p> <p>21 A. Officially, the custodian of records for all</p> <p>22 the licensees, managing office staff and daily</p> <p>23 operations of the board, attending meetings within the</p> <p>24 department on behalf of -- of the board.</p> <p>25 Q. And so what -- what is the Tennessee Board of</p>	<p style="text-align: right;">Page 16</p> <p>1 contaminated epidural steroid injections that were</p> <p>2 imported into Tennessee from a compounding pharmacy</p> <p>3 known as the New England Compounding Center?</p> <p>4 MR. WELLS: Object to form.</p> <p>5 BY MR. NOLAN:</p> <p>6 Q. You can go ahead and answer.</p> <p>7 A. I knew about the circumstances. I didn't know</p> <p>8 about the litigation --</p> <p>9 Q. Okay.</p> <p>10 A. -- until this was served.</p> <p>11 Q. Well, when I ask you questions today, I'm going</p> <p>12 to be asking you about the pharmacy rules and laws as</p> <p>13 they existed in Tennessee in 2011 and in 2012, before</p> <p>14 the fungal meningitis outbreak.</p> <p>15 Do you understand that?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. With that in mind, could you tell us</p> <p>18 what a compounding pharmacy is.</p> <p>19 A. Compounding is defined in state law as the</p> <p>20 prescribing and the preparation of a patient-specific</p> <p>21 drug product.</p> <p>22 Q. Okay. And so what is the difference between a</p> <p>23 compounding pharmacy and a licensed pharmaceutical</p> <p>24 manufacturer?</p> <p>25 A. Manufacturers, of course, would be under FDA</p>
<p style="text-align: right;">Page 15</p> <p>1 Pharmacy?</p> <p>2 A. We are the governing body of pharmacy and the</p> <p>3 profession of pharmacy in Tennessee, promulgate rules</p> <p>4 subject to whatever authority the legislature gives us,</p> <p>5 and we are responsible for compliance and maintaining</p> <p>6 the standards for pharmacy.</p> <p>7 Q. Okay. So the board does promulgate rules and</p> <p>8 regulations that govern pharmacy practice in Tennessee?</p> <p>9 A. Yes.</p> <p>10 Q. And does your job include being familiar with</p> <p>11 the pharmacy rules and laws that apply in Tennessee?</p> <p>12 A. Yes.</p> <p>13 Q. Dr. Grinder, are you aware that this litigation</p> <p>14 that brings us here today arises from a fungal</p> <p>15 meningitis catastrophe that occurred in the fall of</p> <p>16 2012?</p> <p>17 A. I'm not sure -- are you asking did I know this</p> <p>18 litigation was happening, or am I --</p> <p>19 Q. Yes. Are you generally familiar with what the</p> <p>20 litigation is about?</p> <p>21 A. Not other than just from the subpoena being --</p> <p>22 Q. Okay. So did you know that this litigation</p> <p>23 involves a circumstance in which 16 Tennessee plaintiffs</p> <p>24 died and scores of others got sick with fungal</p> <p>25 meningitis or other fungal infections after receiving</p>	<p style="text-align: right;">Page 17</p> <p>1 jurisdiction, and they would be manufacturing bulk</p> <p>2 products; whereas a compounding pharmacy typically would</p> <p>3 be compounding a patient-specific product based on a</p> <p>4 patient -- a prescriber-patient-pharmacy triad.</p> <p>5 Q. Okay. And is it fair to understand that --</p> <p>6 that licensed pharmaceutical manufacturers that receive</p> <p>7 the FDA oversight receive a different degree of</p> <p>8 oversight than do compounding pharmacies?</p> <p>9 MR. TARDIO: Object to the form.</p> <p>10 BY MR. NOLAN:</p> <p>11 Q. You can go ahead and answer.</p> <p>12 (Clarification by the reporter.)</p> <p>13 MR. NOLAN: Mr. Tardio.</p> <p>14 BY MR. NOLAN:</p> <p>15 Q. You can go ahead and answer.</p> <p>16 A. Yes, manufacturers would be under a different</p> <p>17 scrutiny than -- than a pharmacy.</p> <p>18 Q. Okay. So are drugs that are produced by</p> <p>19 licensed manufacturers, such as Pfizer, for example, FDA</p> <p>20 approved?</p> <p>21 A. Yes. If the -- if they're FDA inspected and</p> <p>22 approved, then those drugs would be approved.</p> <p>23 Q. All right. And how is that different from</p> <p>24 drugs that are made by compounding pharmacies pursuant</p> <p>25 to a patient-specific prescription?</p>



DISCOVERY
LITIGATION SERVICES
Court Reporting • Videography • Trial Presentations

Nationwide Coverage

100 Mayfair Royal
181 Fourteenth Street
Atlanta, GA 30309
404.847.0999
www.DiscoveryLit.com

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY
VIDEOTAPED DEPOSITION OF TERRY W. GRINDER, DPH on 09/14/2015

Pages 18..21

<p style="text-align: right;">Page 18</p> <p>1 A. They would not be under FDA scrutiny if they 2 were properly compounded by a pharmacy. 3 Q. And do you know whether the FDA approval 4 process for a company such as Pfizer involves patient 5 safety? 6 MR. WELLS: Object to form. 7 THE WITNESS: I'm not sure I understand 8 that one. 9 BY MR. NOLAN: 10 Q. Well, let me ask you this: Before the fungal 11 meningitis catastrophe, specifically, what did the law 12 require in terms of how compounding pharmacies were 13 permitted to make and distribute medications in 14 Tennessee? 15 MR. TARDIO: Object to the form. 16 THE WITNESS: Okay. Compounding was 17 defined, and it involved the triad, as we mentioned 18 before, of prescriber-patient-pharmacy. Typically, it 19 was a patient-specific order that would have not been 20 commercially available, and that also allowed for 21 anticipatory compounding, based on prescribing habits of 22 that prescriber. 23 BY MR. NOLAN: 24 Q. Okay. And -- and this triad of prescriber, 25 patient, and pharmacy, is that arrangement set up for</p>	<p style="text-align: right;">Page 20</p> <p>1 MR. TARDIO: Object to the form. 2 BY MR. NOLAN: 3 Q. You can go ahead and answer. 4 MS. FUIG: Counsel, this is Yvonne. May I 5 interrupt only briefly? Is he looking at one in force 6 and effect in 2012 or currently? 7 MR. NOLAN: He's looking at the one that 8 was in force in 2012 that became effective on August 9 11th, 2010. 10 MS. FUIG: Very good. Thank you so much. 11 I'm going to pull it up. 12 MR. NOLAN: Sure. 13 MS. FUIG: Thank you. 14 BY MR. NOLAN: 15 Q. So let me ask it this way: What does this law 16 do? 17 A. It allows a pharmacy to provide a specific 18 medication for patients that might not otherwise be able 19 to use the next nearest commercially available product. 20 Q. Okay. And so how many circumstances does it 21 list here in which it's appropriate to compound a 22 medication? 23 A. (A), (B), and (C); it'd be three. 24 Q. Okay. And so let's talk about circumstance 25 (A). What is that circumstance when it's appropriate to</p>
<p style="text-align: right;">Page 19</p> <p>1 the purpose of protecting patient safety? 2 A. Yes. 3 Q. And how does it promote patient safety? 4 A. It would allow a pharmacy to compound a 5 specific product for a patient that might not be able to 6 use the next nearest commercially available product, and 7 it would allow the oversight of the Board of Pharmacy in 8 that process. 9 Q. Okay. And so where is this -- this law about 10 the circumstances under which compounding is legal? 11 Where is it found? 12 A. Compounding is defined, I believe, in T.C.A. 13 63-10. And I don't have a copy with me, but I believe 14 it would be under "Definitions" in that section. 15 Q. Let me hand you a document that we're going to 16 make Exhibit No. 573. And for the record, this is 17 T.C.A. 63-10-204. 18 (Exhibit No. 573 was marked.) 19 BY MR. NOLAN: 20 Q. And let me first ask you whether this is the 21 law that you were mentioning a moment ago. 22 A. Yes, it is. 23 Q. Okay. And so this law defines when 24 it's appropriate to engage in compounding; is that 25 correct?</p>	<p style="text-align: right;">Page 21</p> <p>1 compound a drug? 2 A. That, again, is the triad as a result of the 3 prescription order initiative based on the 4 prescriber-patient-pharmacist relationship in the course 5 of professional practice. 6 Q. Okay. Now, let's look at circumstance (B), and 7 I'm going to read that into the record. 8 A. Okay. 9 Q. It says: "In anticipation of prescription 10 orders based on routine, regularly observed prescribing 11 patterns." 12 Have I read that correctly? 13 A. Yes. 14 Q. Okay. And is that the circumstance that you 15 mentioned involving anticipatory compounding? 16 A. Yes. 17 Q. So am I correct in understanding that if a 18 particular compounding pharmacy has a customer -- say, 19 Dr. Smith, for example -- and they know that Dr. Smith 20 writes ten patient-specific prescriptions for a 21 particular medication each week, it's okay for that 22 pharmacy to, on Monday morning, compound ten vials of 23 that particular medicine anticipating that they will 24 actually receive ten patient-specific orders as is 25 Dr. Smith's custom?</p>



DISCOVERY
LITIGATION SERVICES
Court Reporting • Videography • Trial Presentations

Nationwide Coverage

100 Mayfair Royal
181 Fourteenth Street
Atlanta, GA 30309
404.847.0999
www.DiscoveryLit.com

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY
VIDEOTAPED DEPOSITION OF TERRY W. GRINDER, DPH on 09/14/2015

Pages 22..25

<p style="text-align: right;">Page 22</p> <p>1 MR. TARDIO: Object to the leading.</p> <p>2 BY MR. NOLAN:</p> <p>3 Q. You can go ahead and answer.</p> <p>4 MR. WELLS: Object to form.</p> <p>5 THE WITNESS: Yes.</p> <p>6 BY MR. NOLAN:</p> <p>7 Q. Okay. So that -- that type of "in anticipation</p> <p>8 of prescription" orders based upon routine, regularly</p> <p>9 observed prescribing patterns, does it allow for the</p> <p>10 making of compounded medications in bulk and sending</p> <p>11 them to some customer without ever receiving</p> <p>12 patient-specific prescriptions?</p> <p>13 A. That was not the idea when the -- when this</p> <p>14 particular clause was put in, but I'm not an attorney.</p> <p>15 I can't --</p> <p>16 Q. Okay. Well, since you've been there, or before</p> <p>17 the fungal men- -- meningitis outbreak, has this</p> <p>18 language, "In anticipation of prescription orders based</p> <p>19 on routine, regularly observed prescribing patterns,"</p> <p>20 always been in this particular law, to your knowledge?</p> <p>21 MR. WELLS: Object to form.</p> <p>22 THE WITNESS: For as long as I recall,</p> <p>23 yes.</p> <p>24 BY MR. NOLAN:</p> <p>25 Q. Okay. And then am I right that the third</p>	<p style="text-align: right;">Page 24</p> <p>1 MR. NOLAN: Of the statute?</p> <p>2 MR. KRAUSE: Do you not have one? We've</p> <p>3 got one here.</p> <p>4 MR. NOLAN: We've got one.</p> <p>5 THE WITNESS: There is your (tendering)...</p> <p>6 MR. WELLS: Thank you.</p> <p>7 BY MR. NOLAN:</p> <p>8 Q. Could you hold that up to the camera and just</p> <p>9 explain --</p> <p>10 A. Sure.</p> <p>11 Q. -- this to us, what this means.</p> <p>12 A. As the patient sees the prescriber, proper</p> <p>13 treatment is determined, an order is sent to the</p> <p>14 pharmacy specific for that patient, and the pharmacy</p> <p>15 dispenses it to the patient.</p> <p>16 Q. I see. Let me make that Exhibit No. 574.</p> <p>17 (Exhibit No. 574 was marked.)</p> <p>18 MS. HAMPTON: I'm sorry; may I see that?</p> <p>19 MR. NOLAN: Yes, you can.</p> <p>20 BY MR. NOLAN:</p> <p>21 Q. Let me hand you a document that we're going to</p> <p>22 make 575.</p> <p>23 (Exhibit No. 575 was marked.)</p> <p>24 BY MR. NOLAN:</p> <p>25 Q. And, sir, I'm going to represent to you that</p>
<p style="text-align: right;">Page 23</p> <p>1 circumstance listed here, does that involve research or</p> <p>2 testing or -- or analysis-type endeavors?</p> <p>3 A. It does.</p> <p>4 Q. Is that -- what is that, like clinical trials?</p> <p>5 Or what sort of circumstance does that come up in?</p> <p>6 A. It could be the drug researches or teaching</p> <p>7 purposes or for chemical analysis, but it's not subject</p> <p>8 to sale or dispensing.</p> <p>9 Q. And does the individual prescription rule, as</p> <p>10 found in this statute, allow for the making of -- of</p> <p>11 bulk medications by compounders for distribution without</p> <p>12 individual prescriptions?</p> <p>13 MR. TARDIO: Object to the form.</p> <p>14 MR. WELLS: Object to form.</p> <p>15 MR. TARDIO: Asked and answered.</p> <p>16 BY MR. NOLAN:</p> <p>17 Q. You can go ahead.</p> <p>18 A. Back to the triad analogy, if any of the three</p> <p>19 are missing, it would not be typical compounding.</p> <p>20 Q. Could I give you a piece of paper, if I could,</p> <p>21 and ask you to just maybe draw for us kind of a</p> <p>22 conceptual representation of this triad that you're</p> <p>23 mentioning (tendering).</p> <p>24 A. Sure (drawing).</p> <p>25 MR. WELLS: Is that an extra copy, George?</p>	<p style="text-align: right;">Page 25</p> <p>1 this is a -- this is a document that has been produced</p> <p>2 in the context of this litigation to us, and it's</p> <p>3 labeled "Prescription Order Form" at the top. And you</p> <p>4 see NECC's logo there. And the date is July 24th of</p> <p>5 2012.</p> <p>6 Now, as you look at this document, do you see</p> <p>7 that it appears to be placing an order for two drugs,</p> <p>8 one of which is called methylprednisolone? Do you see</p> <p>9 that?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And how many units of this drug are</p> <p>12 being requested apparently by this order form?</p> <p>13 A. It says 500 units.</p> <p>14 Q. Okay. And you see where there is a column for</p> <p>15 the names of patients?</p> <p>16 A. Yes.</p> <p>17 Q. And so how many patient names do you see listed</p> <p>18 on that column?</p> <p>19 A. None.</p> <p>20 Q. Okay. Does this order form comply with</p> <p>21 Tennessee law as far as you're concerned?</p> <p>22 MR. TARDIO: Object to the form.</p> <p>23 MR. WELLS: Object to form.</p> <p>24 MR. TARDIO: Object to the undisclosed</p> <p>25 expert testimony and legal conclusions.</p>



DISCOVERY
LITIGATION SERVICES
Court Reporting • Videography • Trial Presentations

Nationwide Coverage

100 Mayfair Royal
181 Fourteenth Street
Atlanta, GA 30309
404.847.0999
www.DiscoveryLit.com

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY
VIDEOTAPED DEPOSITION OF TERRY W. GRINDER, DPH on 09/14/2015

Pages 26..29

<p style="text-align: right;">Page 26</p> <p>1 BY MR. NOLAN:</p> <p>2 Q. You can go ahead and answer.</p> <p>3 A. This wouldn't meet several of our requirements</p> <p>4 for a prescription order.</p> <p>5 Q. Could you tell us what requirements that does</p> <p>6 not meet for a prescription order.</p> <p>7 A. Number one would be the name of the patient.</p> <p>8 Q. Okay.</p> <p>9 A. Directions for use.</p> <p>10 Q. Okay.</p> <p>11 A. And that's -- that'd be the main thing to make</p> <p>12 it more compliant with a prescription order.</p> <p>13 Q. Okay. Now, I'm going to represent to you that,</p> <p>14 in addition to using order forms like the one you have</p> <p>15 in front of you, one of the parties in this case, at the</p> <p>16 request of NECC, occasionally sent lists of patient</p> <p>17 names to NECC that did not necessarily correspond with</p> <p>18 who would receive the drug.</p> <p>19 So they didn't send a list every time they used</p> <p>20 an order form like that. And the few times that they</p> <p>21 did send a list, the names on the list did not mean that</p> <p>22 the patients would actually receive that particular</p> <p>23 medication. Okay?</p> <p>24 From a regulatory standpoint in Tennessee, does</p> <p>25 that arrangement comply with the pharmacy rules as you</p>	<p style="text-align: right;">Page 28</p> <p>1 who would receive MPA from that particular pharmacy.</p> <p>2 Do you understand so far what I've explained?</p> <p>3 A. Yes.</p> <p>4 Q. Does that comply with the Tennessee rules and</p> <p>5 laws as you understand them?</p> <p>6 MR. TARDIO: Same objections.</p> <p>7 THE WITNESS: That would not meet the</p> <p>8 requirement for compounding.</p> <p>9 BY MR. NOLAN:</p> <p>10 Q. Do you know why in the world a compounding</p> <p>11 pharmacy would ask a customer to send a random list of</p> <p>12 patient names?</p> <p>13 MR. TARDIO: Object to the form.</p> <p>14 MR. WELLS: Object to form.</p> <p>15 THE WITNESS: Any -- any answer I would</p> <p>16 have would only be speculation and...</p> <p>17 BY MR. NOLAN:</p> <p>18 Q. Okay. So if a -- if a company planned to sell</p> <p>19 medications in Tennessee in bulk without individual</p> <p>20 patient-specific prescriptions, what type of license</p> <p>21 would the company need?</p> <p>22 A. A manufacturer's license.</p> <p>23 Q. Okay. And so is that the type of license that</p> <p>24 would be required to sell FDA-approved drugs such as</p> <p>25 Depo-Medrol made by Pfizer, for example?</p>
<p style="text-align: right;">Page 27</p> <p>1 understand them?</p> <p>2 MR. TARDIO: Object to the form.</p> <p>3 MR. WELLS: Object to form.</p> <p>4 MR. TARDIO: Object to the opinion</p> <p>5 testimony and legal conclusions.</p> <p>6 BY MR. NOLAN:</p> <p>7 Q. You can go ahead and answer.</p> <p>8 A. Can we clarify exactly what you're asking?</p> <p>9 Q. Sure. What I'm saying is that at some point --</p> <p>10 I'm saying that one of the parties in this case, a</p> <p>11 party called Saint Thomas Outpatient Neurosurgical</p> <p>12 Center, began buying vials of what we call MPA,</p> <p>13 methylprednisolone acetate, using order forms like this</p> <p>14 that didn't have patient names on them.</p> <p>15 A. Okay.</p> <p>16 Q. And that at some point in time, one of the</p> <p>17 sales reps for NECC asked the facility to send lists of</p> <p>18 patients. And the facility explained, Well, we really</p> <p>19 can't do that. We have lists we can print out, but that</p> <p>20 doesn't necessarily correspond with who's going to</p> <p>21 receive these particular shots. And the sales rep said,</p> <p>22 That's okay; just send the list anyway.</p> <p>23 And then the local facility, the Saint Thomas</p> <p>24 Outpatient Neurosurgical Center, sent some patient</p> <p>25 lists, even though they didn't necessarily match up with</p>	<p style="text-align: right;">Page 29</p> <p>1 A. That would be either a manufacturer or a</p> <p>2 wholesaler license.</p> <p>3 Q. Okay. And what type of license did NECC have?</p> <p>4 A. A pharmacy license.</p> <p>5 Q. All right. So was NECC authorized to sell</p> <p>6 medications in bulk in Tennessee without</p> <p>7 patient-specific prescriptions?</p> <p>8 A. They were not properly licensed to do so.</p> <p>9 Q. Now, has -- has your job ever included</p> <p>10 answering phone calls from healthcare providers who have</p> <p>11 questions about pharmacy laws?</p> <p>12 A. Very much so.</p> <p>13 Q. All right. And do you remember receiving a</p> <p>14 phone call from a pharmacist named Martin Keivas, who</p> <p>15 was the Director of Pharmacy Services at Saint Thomas</p> <p>16 Hospital in early 2011?</p> <p>17 A. I don't recall that specific call or, you know,</p> <p>18 any specific conversation.</p> <p>19 Q. All right. So does that mean that no such call</p> <p>20 occurred, or does it mean maybe there was a call and you</p> <p>21 talk to a lot of people and you don't remember every</p> <p>22 single call that you --</p> <p>23 A. We have lots of calls daily from lots of</p> <p>24 different people, and I just can't recall the specifics.</p> <p>25 Q. All right. Well, I'll represent to you that</p>



DISCOVERY
LITIGATION SERVICES
Court Reporting • Videography • Trial Presentations

Nationwide Coverage

100 Mayfair Royal
181 Fourteenth Street
Atlanta, GA 30309
404.847.0999
www.DiscoveryLit.com

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY
VIDEOTAPED DEPOSITION OF TERRY W. GRINDER, DPH on 09/14/2015

Pages 30..33

<p style="text-align: right;">Page 30</p> <p>1 Dr. Kelvas has already given some testimony in this case</p> <p>2 and that during that testimony, he explained that in</p> <p>3 March of 2011, a New England Compounding Center sales</p> <p>4 representative came and met with him and solicited the</p> <p>5 hospital's business and tried to sell the hospital</p> <p>6 compounded medications.</p> <p>7 And he didn't think that that arrangement was</p> <p>8 appropriate or legal, so he called the Tennessee Board</p> <p>9 of Pharmacy, and he talked with you. And according to</p> <p>10 him, you basically explained two things: First, that</p> <p>11 medications could only be procured from a compounding</p> <p>12 pharmacy pursuant to a patient-specific prescription</p> <p>13 involving the three-way relationship that you've</p> <p>14 explained.</p> <p>15 A. Uh-huh.</p> <p>16 Q. And secondly, that medications can only be</p> <p>17 purchased without prescriptions from someone with a</p> <p>18 manufacturer's license.</p> <p>19 Is that -- is Mr. Kelvas's description in that</p> <p>20 regard consistent with what you would typically tell</p> <p>21 people back in the 2011 time frame?</p> <p>22 MR. TARDIO: Object to the form.</p> <p>23 MR. WELLS: Object to form.</p> <p>24 BY MR. NOLAN:</p> <p>25 Q. You can go ahead and answer.</p>	<p style="text-align: right;">Page 32</p> <p>1 pharmacist or the manager or director of an ambulatory</p> <p>2 surgery center?</p> <p>3 MR. TARDIO: Object to the form.</p> <p>4 BY MR. NOLAN:</p> <p>5 Q. You can go ahead and answer.</p> <p>6 A. Yes.</p> <p>7 Q. Let me hand you a -- a document that we've</p> <p>8 already made Exhibit No. 526 in this litigation. And,</p> <p>9 Dr. Grinder, I'm going to represent to you that this is</p> <p>10 a document that was produced to us by the Saint Thomas</p> <p>11 Outpatient Neurosurgical Center, and it consists of some</p> <p>12 of the written information that the New England</p> <p>13 Compounding Center provided to that particular clinic.</p> <p>14 Okay?</p> <p>15 And if we look on the second page, you see</p> <p>16 paragraph G, which reads "Dispensing"?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And I want to read it into the record.</p> <p>19 It says, "Product is dispensed by patient-specific</p> <p>20 prescription only. There must be a specific</p> <p>21 practitioner-patient-pharmacist relationship to dispense</p> <p>22 to an individual patient or facility."</p> <p>23 Have I read that correctly?</p> <p>24 A. Yes.</p> <p>25 Q. And is that statement consistent with or</p>
<p style="text-align: right;">Page 31</p> <p>1 A. Yes.</p> <p>2 Q. Okay.</p> <p>3 MS. PUIG: Mr. Nolan, could you repeat the</p> <p>4 question. At the middle of it, your voice trailed off.</p> <p>5 MR. NOLAN: I think it would be best if we</p> <p>6 had the court reporter read back the question.</p> <p>7 MS. PUIG: Very good. Thank you so much.</p> <p>8 (Requested portion read.)</p> <p>9 MR. NOLAN: And could you go ahead and</p> <p>10 read the answer.</p> <p>11 COURT REPORTER: The answer was "yes."</p> <p>12 BY MR. NOLAN:</p> <p>13 Q. So when -- back in the 2011 time frame, if</p> <p>14 someone called with a question about buying medications</p> <p>15 from a compounding pharmacy, what would you typically</p> <p>16 tell them?</p> <p>17 A. We would have told them that a compounding</p> <p>18 pharmacy could only dispense products that's prepared</p> <p>19 under the triad definition of compounding, and it had to</p> <p>20 be patient specific.</p> <p>21 Q. And is that the explanation that you would give</p> <p>22 to anyone who would call with a question like that?</p> <p>23 A. Yes, it is.</p> <p>24 Q. Okay. So would that mean you would give the</p> <p>25 same answer, whether the person calling is a hospital</p>	<p style="text-align: right;">Page 33</p> <p>1 similar to what you would tell people if they called</p> <p>2 your office with questions about how compounding</p> <p>3 pharmacies were supposed to work?</p> <p>4 A. It would be.</p> <p>5 Q. Now, I'd like to talk with you for a moment, if</p> <p>6 I could, about the rules that apply to the -- the</p> <p>7 labeling of compounded medications.</p> <p>8 Are you generally familiar with those rules?</p> <p>9 A. Yes.</p> <p>10 Q. And could you tell us basically how compounded</p> <p>11 medications were supposed to be labeled if they were</p> <p>12 being distributed to patients in Tennessee.</p> <p>13 A. A prescription label should include at least</p> <p>14 the patient's name, drug name and strength, and</p> <p>15 directions for use, as well as the date it was</p> <p>16 dispensed.</p> <p>17 Q. And have you brought with you today a vial of</p> <p>18 methylprednisolone acetate that the Tennessee Board of</p> <p>19 Pharmacy procured during its inspection of the Saint</p> <p>20 Thomas Outpatient Neurosurgical Center?</p> <p>21 A. Actually, it was procured, I think, by the</p> <p>22 Department of Health --</p> <p>23 Q. Okay.</p> <p>24 A. -- not the Board of Pharmacy. But, yes, I do</p> <p>25 have a vial.</p>



DISCOVERY
LITIGATION SERVICES
Court Reporting • Videography • Trial Presentations

Nationwide Coverage

100 Mayfair Royal
181 Fourteenth Street
Atlanta, GA 30309
404.847.0999
www.DiscoveryLit.com